No. 31015/69/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A Wing, Shastri Bhawan,
New Delhi 110 001

Subject: **Review application of M/s Sun Pharma Laboratories Limited against price fixation of their formulations "Sodium Valproate - CR Tablets 300mg and Sodium Valproate - CR Tablets 500mg" vide NPPA order No. S.O. 1687(E), dated 24.05.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

Ref: **1) Review application, dated 20.06.2017**
2) NPPA notification under review S.O. No.1687(E), dated 24.05.2017
3) Record Note of discussions held in the personal hearing on 10.10.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharma Laboratories Limited (hereinafter called the petitioner) against notification S.O. No.1687(E), dated 24.05.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Sodium Valproate - CR Tablets 300mg and Sodium Valproate - CR Tablets 500mg.

2. The petitioner has contended as under:

I. Company is aggrieved by the said notification of Sodium Valproate CR Tablet 300mg, and CR 500 mg tablets on the following grounds:-

(i) The draft working sheet of Sodium Valproate 300 mg CR Tablet, Sodium Valproate 500 mg CR Tablet was displayed on the NPPA website on 27.02.2017.

(ii) In the draft working sheet of Sodium Valproate 300 mg CR Tablet, company's product pack Encorate Chrono 300 was not included in the ceiling price calculation. Similarly, in the draft working sheet of Sodium Valproate 500 mg CR Tablet, company's product pack Encorate Chrono 500 was not included in the ceiling price calculation. Company had submitted our representation dated 09.03.2017 against the draft working sheet of these 2 formulations within 10 working days.

(iii) However, in the ceiling price notification NPPA S.O. No. 1687(E) dated 24.05.2017, working sheet of which was displayed on NPPA website on 29.05.2017; company's products were not included though they had filed representation for the same.

II. **Sodium Valproate CR Tablet 300mg** –

(i) The working sheet shows composition as per NLEM as Sodium Valproate + Valproic Acid in 19 out of 22 products considered for calculation of Ceiling Price. However, as per Schedule I annexed to DPCO 2013 it is only Sodium Valproate CR

Tablet 300mg and it does not mention Sodium Valproate + Valproic Acid at all, hence these should be excluded from the ceiling price calculation.

(ii) Sodium Valproate and Valproic Acid both are active ingredients. Single ingredient formulations of Sodium Valproate are available in the market, as also shown in the working sheet Sl. No. 3,8 for Sodium Valproate, and only these 2 formulations should have been considered in the ceiling price calculation.

(iii) Single ingredient formulations of Valproic Acid are available in the market as also shown in the working sheet Sl. No. 9, which should not be included in ceiling price calculation.

(iv) There are separate monographs for products containing Sodium Valproate and Valproic acid in IP (eg. Sodium Valproate Tablets, Valproic acid Capsules). It may be noted that in Sodium Valproate formulations, description is mentioned as 'Sodium Valproate Tablets contain not less than 95.0 % and not more than 105.0% of the stated amount of sodium valproate' and for Valproic acid formulations, description is mentioned as 'Valproic Acid Capsules contain not less than 90.0 % and not more than 110.0% of the stated amount of Valproic acid)'.

(v) Accordingly Controlled Release formulations having composition of combination of Sodium Valproate and Valproic Acid should not be included in the Ceiling Price Calculation.

(vi) Since ceiling price for this formulation was being notified for the first time, WPI should not have been factored while calculating the ceiling price, as per provision of DPCO 2013.

III. **Sodium Valproate CR Tablet 500mg** –

(i) The working sheet shows composition as per NLEM as Sodium Valproate + Valproic Acid in 21 out of 23 products considered for calculation of Ceiling Price. However, as per Schedule I annexed to DPCO 2013 it is only Sodium Valproate CR Tablet 500mg and it does not mention Sodium Valproate + Valproic Acid at all, hence these should be excluded from the ceiling price calculation.

(ii) Sodium Valproate and Valproic Acid both are active ingredients. Single ingredient formulations of Sodium Valproate are available in the market, as also shown in the working sheet Sl. No. 9 for Sodium Valproate, and only this formulation should have been considered in the ceiling price calculation.

(iii) Single ingredient formulations of Valproic Acid are available in the market as also shown in the working sheet Sl. No. 10, which should be excluded from the ceiling price calculation.

(iv) There are separate monographs for products containing Sodium Valproate and Valproic acid in IP (eg. Sodium Valproate Tablets, Valproic acid Capsules). It may be noted that in Sodium Valproate formulations, description is mentioned as 'Sodium Valproate Tablets contain not less than 95.0 % and not more than 105.0% of the stated amount of sodium valproate' and for Valproic acid formulations, description is

mentioned as 'Valproic Acid Capsules contain not less than 90.0 % and not more than 110.0% of the stated amount of Valproic acid)'.

(v) Accordingly Controlled Release formulations having composition of combination of Sodium Valproate and Valproic Acid should not be included in the Ceiling Price Calculation.

(vi) Since ceiling price for this formulation was being notified for the first time, WPI should not have been factored while calculating the ceiling price, as per provision of DPCO 2013.

IV. In view of above, Company requested this Department to issue necessary directives to re-notify the ceiling price of Sodium Valproate 300 mg CR Tablet, Sodium Valproate 500 mg CR Tablet.

3. **Comments of NPPA:**

I. Ceiling price of **Sodium Valproate – CR tablet 300mg and 500mg** was notified as Rs. 5.73/tablet and 8.82/tablet vide S.O. 1687(E) dated 24.05.2017 and revised to Rs. 5.50/tablet and Rs. 8.46/tablet vide S.O. 2058(E) dated 30.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Sodium Valproate – CR tablet 300mg and 500mg**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	**Sodium Valproate CR Tablet 300mg and 500 mg:** Company has stated that NPPA has not considered their product Encorate Chrono 300 mg and Encorate Chrono 500 mg in the ceiling price calculation for subject formulation.	NPPA fixed the ceiling price Rs. 5.73/tablet and 8.82/tablet vide S.O. 1687(E) dated 24.05.2017 and revised to Rs. 5.50/tablet and Rs. 8.46/tablet (GST effect) based on the data provided by AIOCD-AWACS for the month of August, 2015. NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. M/s. Sun Pharma Laboratories Limited made representation against the proposed ceiling price. NPPA examined the same. As company did not submit requisite documents/information as per OM No. 8(34)/Div.II/NPPA dated 07.02.2017. Therefore, the same was not considered by the authority.

2.	With respect to Sodium Valproate CR tablet 300 mg and 500 mg, Company further stated as below: NPPA has considered 22 packs for fixing the ceiling price of subject formulation in respect of Sodium Valproate 300 mg CR tab and 23 packs in respect of Sodium Valproate 500 mg CR tab. Out of them, 19 contain Sodium Valproate + Valporic acid in case of Sodium Valproate 300 mg CR tab and 21 contain Sodium Valproate + Valporic acid in case of Sodium Valproate 500 mg CR tab. However, as per schedule I, it is only Sodium Valproate CR tablet 300mg and 500 mg and it does not mention Sodium Valproate + Valporic Acid, therefore, all the packs containing Sodium Valproate + Valporic Acid should be excluded from the ceiling price calculation. Company also pointed out that Sodium Valproate + Valporic Acid both are active ingredients. Single ingredient formulations of Sodium Valproate are available in the market and as per the opinion of the company, packs containing Sodium Valproate should have been considered in the ceiling price calculation. Company is also of the opinion that single ingredient formulation of Valporic Acid are available in the market, therefore, formulations containing Valporic Acid should not be included in ceiling price calculation. There are separate monographs for products containing Sodium Valproate and Valporic Acid (example Sodium Valproate tablets and Valporic Acid capsules). In case of Sodium Valproate tablet, limit is not less than 95% and not more than 105% while in case of Valporic Acid formulation (Valporic Acid	Issue raised by company has no merit. Sodium Valproate CR tablet 300mg was included in NLEM 2015. DPCO does not differentiate the API used in manufacturing pharmaceuticals products. Valporic Acid, its salts and esters are used in the treatment of various type of Epilepsy. Manufacturer may use API Sodium Valproate 300mg or Sodium Valproate 200mg + Valporic Acid 87mg (both together correspondence to Sodium Valproate 300mg). Therefore, company's request to exclude the packs containing Sodium Valproate or formulation containing Valporic Acid is not acceptable. NPPA fixed the ceiling price for subject formulation in accordance with the provisions of DPCO, 2013. Not related with the provisions of DPCO, 2013.

	Capsule), limit is not less than 90% and not more than 110% in terms of the stated amount of Valporic Acid.	
3.	Since, ceiling price for this formulation was being notified for the first time, WPI should not have been factored while calculating the ceiling price.	NPPA has been consistently following the implementation of WPI reduction factor in terms of the decision taken by the Authority in its 27th Authority Meeting held on 29.03.2016.

III. Company has not challenged any notification in respect of **Sodium Valproate – CR tablet 300mg and 500mg**.

4. During personal hearing company representative has submitted following:

- Formulations having composition of combination of Sodium Valproate and Valproic Acid is not listed in Schedule I of DPCO 2013 as amended on 10.03.2016 and therefore are not Scheduled Formulation as per Para 2(zb) of DPCO 2013
- Accordingly such formulations should not be included in the Ceiling Price Calculation.
- The company representative requested the authority to give necessary directives to NPPA to take the opinion of Expert Committee on whether formulation having composition of combination of Sodium Valproate and Valproic Acid is a scheduled drug or not and fix the ceiling price of Sodium Valproate CR Tablet 300mg accordingly.
- In case Committee of Experts recommends that the formulation having composition of combination of Sodium Valproate and Valproic Acid is a scheduled drug, then our product pack Encorate Chrono 300 having more than 1% market share and PTR of Rs.52.34 as per our representation dated 09.03.2017, should be included in ceiling price calculation.
- Since ceiling price for this formulation was being notified for the first time, WPI should not have been factored while calculating the ceiling price

4.2 NPPA representative stated that they have no further comments in addition to as stated above.

5. <u>Examination:</u>

In the instant case, the company claimed that the MAT values of their two formulations Encorate Chrono 300mg and Encorate Chrono 500mg, containing Sodium Valproate CR tablets, should be considered while arriving at the average ceiling prices of the formulations under consideration. The company has submitted documentary proof in support of its claim, which are placed at pages 1-13/cors. On going through the documentary proof submitted by the company, it is observed that the claim of the company has got merit.

5.2 As regards company's claim that formulations containing Valporic Acid should not be included in ceiling price calculation, has got no merit. Sodium Valproate CR tablet 300mg was included in NLEM 2015. DPCO does not differentiate the API used in manufacturing pharmaceuticals products. Valporic Acid, its salts and esters are used in

the treatment of various type of Epilepsy. Manufacturer may use API Sodium Valproate 300mg or Sodium Valproate 200mg + Valporic Acid 87mg (both together correspondence to Sodium Valproate 300mg). Therefore, company's request to exclude the packs containing Sodium Valproate or formulation containing Valporic Acid is not acceptable. NPPA fixed the ceiling price for subject formulation in accordance with the provisions of DPCO, 2013.

5.3 The company claimed that the ceiling price was notified for the first time, hence while fixing the ceiling prices for the Sodium Valproate CR Tablet 300mg and Sodium Valproate CR Tablet 500mg, WPI should not have factored. The claim of the company has got no merit as the base data considered for fixing the ceiling price was of August, 2015.

6. **Government Decision:**

"NPPA is hereby directed to consider refixing/revising the ceiling price of Sodium Valproate CR tablets 300mg and 500mg. after verification of information/documentary proof submitted by the petitioner company, in respect of MAT value of their two products Encorate Chrono 300mg 500mg containing the Sodium Valproate, on merit."

"Company's claim that formulations containing Valporic Acid should not be included in ceiling price calculation, has got no merit, and stands rejected, as DPCO does not differentiate the API used in manufacturing pharmaceuticals products, containing Sodium Valproate CR and Valporic Acid in NLEM 2015."

"Further, the claim of the company that since ceiling price was notified for the first time, WPI should not have factored while fixing the ceiling prices for the Sodium Valproate CR Tablet 300mg and Sodium Valproate CR Tablet 500mg, has got no merit as the base data considered for fixing the ceiling prices was of August, 2015."

Issued on this date of 28th day of November, 2017.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

To

1. **M/s. Sun Pharma Laboratories Limited,**
   Sun House, Plot No.201 B/1,
   Western Express Highway, Goregaon (E),
   Mumbai-400063.
2. **The Member Secretary,**
   National Pharmaceutical Pricing Authority,
   YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. **PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
2. **PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
3. **T.D., NIC for uploading the order on Department's Website**